

Case 11. Another Public-Private Partnership

Dr. Whatshername is the program officer in the keratin program and a nail polish company approaches her to co-fund a program for research and training in fingernail biology. They want to give money to the institute to fund research in very specific projects and to meet with institute officials to help identify candidates for well-paid and highly publicized fellowships. They'd like the fellowship to be identified as the "keratin/company name" fellowships in fingernail biology. How should Dr. W. proceed?

Is this a partnership?

NIH program priorities can be promoted by relationships by outside organizations in a variety of ways. Two possibilities include: 1) when funds are contributed by the outside organization to the NIH as a gift, thereby increasing the funds available to the NIH to make awards, and 2) when independent awards are made by the outside organization to applications submitted to and reviewed by the NIH, but that have not been funded by the NIH. If the NIH is making the awards, decisions must be made in accordance with institute policies and practices and based on peer review and program priorities. Additional funds received as gifts are awarded and managed just as appropriated funds. Funds awarded by outside organizations, whether based on NIH review results or according to any other criteria, are not NIH awards and follow practices and procedures of the awarding organization. NIH can partner in the awarding of grants by other organizations in many capacities, including in providing advice in the design of the RFA, as reviewers, and as advisers. NIH staff cannot assume fiduciary or financial decision-making or oversight for an outside organization. This applies to both research awards and training awards. (see Guidance for Partnerships for Extramural Funding Initiatives for more information).

Can the arrangement proceed?

Possibly, but only after considering several important issues. Among them:

- Does Dr. W. have any personal financial or interpersonal relationships with the company that are likely to substantially affected by entering into this agreement?
- Will there be a real or apparent conflict of interest as a result of this activity?
- Has she provided equal opportunity and fair access to other companies and/or organizations with similar interests and capabilities (fair access and inclusivity)?
- Is this science consistent with the program and mandate of her IC and program?
- Does the conduct of this research represent an NIH program priority?
- Can this science be accomplished better, more cheaply and/or more rapidly by entering into a partnership?
- Does the design of the relationship ensure that no outside parties unduly influence the allocation of government funds?
- Will there be open and public access to the results of the activity?
- Does the donor/partner receive a *quid pro quo* as a result of the donation/partnership?

Therefore, a donor cannot have the company or organization name attached to the awards if they are NIH awards. The donor can, however, be acknowledged in the RFA and in other documents describing the award as contributing to the NIH's ability to support this award.

Who can make the decision to enter into a partnership?

Extramural program leadership would determine the advisability of entering into this research/training program and develop the necessary agreements and terms. Guidance from the Office of the General Counsel and the Public-Private Partnership Program should be sought to ensure the agreements are consistent with NIH regulations and policies. If a gift is made to the institute, the gift regulations would apply to the acceptance of the gift (see xxx:).

What does it depend on?

The decision to enter into a partnership is, first of all, scientifically driven: ensuring that scientific rigor in the interest of the public health is served in this arrangement. Once that has been determined, the details of the arrangement need to explicitly describe the roles and contributions of all the partners, affirm that U.S. laws and regulations and NIH policies will be adhered to, and define the outcomes of the partnership. If the partnership is limited to a gift to the institute, an MOU may not be needed. If the donor or outside funding agency engages with the institute or program in setting up scientific meetings to examine the scientific basis underlying the program decisions in this subject area, access to the discussion/meeting needs to be open to all appropriate parties (i.e., those with scientific interests in the area and expertise to contribute to the discussion). The science-based decision about whether to proceed will take into consideration of the input from outside parties, including but not limited to that provided by the potential partner. This ensures that the process of government decision-making is not directed by parties who have special or unfair access to the decision-making process.

Can the contributing company or organization receive copies of the applications and/or summary statements from the NIH?

The applicant can convey the application and/or the summary statement to the outside entity, at his or her discretion. The NIH will not, however, transmit the information.

Can representatives from the outside company or organization participate in or observe the review of applications?

To maintain the rigor, confidentiality, and integrity of the peer review process, only individuals who are members of the review panel and NIH staff are permitted to attend the review.

Can the outside organization help the NIH decide which applications to fund and to what level of funding?

The government cannot cede or share the responsibility of deciding how to allocate government funds. Therefore, no outside entity can participate in making initial funding decisions, nor in making yearly decisions regarding continued funding based on progress.

Can he speak on their behalf at scientific meetings?

The RFA can acknowledge that additional support for work in this area (or, specifically, support to extend the funding for this RFA) has been provided by (company name).

What agreements need to be in place?

Partnerships are generally memorialized in Memoranda of Understanding (MOU MC in development) entered into by the parties involved (i.e., the company and the institute). PPP program staff and OGC should be consulted in the development of a partnership and in the drafting and execution of MOUs. If the support is in the form of a gift to the NIH gift fund, see (xxx).

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